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ONE HUNDRED FIFTEENTH CONGRESS
Congress of the United States
House of Representatives
COMMITTEE ON ENERGY AND COMMERCE
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MEMORANDUM

January 18, 2018

To: Subcommittee on Oversight and Investigations, Democratic Members and Staff

Fr: Committee on Energy and Commerce Democratic Staff

Re: Hearing on "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process"

On **Friday, January 19, 2018, at 9:00 a.m. in room 2123 of the Rayburn House Office Building**, the Subcommittee on Oversight and Investigations will hold a hearing entitled "Safety of the U.S. Food Supply: Continuing Concerns Over the Food and Drug Administration's Food-Recall Process." The hearing will focus on issues related to the U.S. Food and Drug Administration's (FDA) oversight of food recalls and its use of new recall authority under the FDA Food Safety Modernization Act (FSMA).

I. FDA OVERSIGHT OF FOOD RECALLS

The Federal Food, Drug, and Cosmetic Act charges FDA with safeguarding the nation's food supply. When FDA learns that a food product is potentially hazardous, it may inform the manufacturing firm, at which point the firm may choose to issue a voluntary recall, or FDA may request a recall.[1] Under relatively recent authority granted by FSMA, FDA can also issue mandatory recalls.[2] However, FDA generally relies on firms to voluntarily recall food products that are potentially hazardous.[3]

Once a recall is initiated, FDA is tasked with overseeing the recall process. FDA conducts a health hazard evaluation for each recall, which it uses to classify the recall based on the level of health hazard posed by the product.[4] FDA's recall classifications range from Class I

[1] 21 C.F.R. § 7.45.

[2] FDA Food Safety Modernization Act, Pub. L. No. 111-353: §206 (2011).

[3] 21 C.F.R. § 7.40.

[4] 21 C.F.R. § 7.41.

through Class III. Class I represents the most serious classification, which is "a reasonable probability that the use of, or exposure to, a violative product will cause serious adverse health consequences or death."[5] FDA then monitors the firm's efforts to remove or recall the offending product(s), and may recommend changes to the firm's recall strategy.[6] As part of this monitoring, FDA requests status reports from the firm, such as information on the consignees (i.e., distributors and retailers of the product) initially notified about the recall.[7] FDA terminates a recall once it determines that the product has been removed, or correction has been made commensurate with the level of hazard posed by the product.[8]

II. PREVIOUS COMMITTEE ACTION ON FOOD RECALLS

The Committee has a long-standing history of conducting oversight of FDA's management of food recalls. For example, over a decade ago, a committee investigation found that FDA lacked sufficient resources and authority to ensure food safety. The Committee explored numerous incidents involving food safety, and held several hearings on the subject.[9] In 2010, the Committee again found that FDA had limited authority to ensure compliance and did not always take swift action in response to violations.[10] Based in part on this work, in late 2010 Congress passed FSMA, which significantly reformed FDA's overall approach to food safety, and gave FDA the authority to order a firm to recall food in certain cases.[11]

To issue a mandatory recall, FDA must first determine that there is reasonable probability that a food is adulterated or misbranded and poses a risk of serious adverse health consequences. FDA must then provide the firm with the opportunity to recall the product. If the firm refuses to do so, FDA may use its authority to order the firm to cease distribution and recall the product, i.e., remove it from the shelves.[12]

III. RECENT OIG FINDINGS

In December 2017, a report by the Office of Inspector General (OIG) for the U.S. Department of Health and Human Services found that FDA still did not always adequately

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[5] 21 C.F.R. § 7.3(m)(1).

[6] 21 C.F.R. § 7.46.

[7] 21 C.F.R. § 7.53.

[8] 21 C.F.R. § 7.55.

[9] House Committee on Energy and Commerce, *Diminished Capacity: Can the FDA Assure the Safety and Security of the Nation's Food Supply?*, 110th Cong. (July 17, 2007).

[10] House Committee on Energy and Commerce, *The Role and Performance of FDA in Ensuring Food Safety*, 111th Cong. (May 6, 2010).

[11] FDA Food Safety Modernization Act, Pub. L. No. 111-353: §206.

[12] *Id.*

oversee food recalls.[13] OIG reported that FDA did not always effectively monitor firms during a recall, such as ensuring that firms initiate recalls promptly. OIG also found shortcomings in FDA meeting its own responsibilities, such as evaluating health hazards timely and collecting accurate data for the purposes of monitoring recalls.[14] Moreover, OIG found that FDA used its new authority under FSMA to issue mandatory recalls only twice between 2011 and August 2016.[15] OIG's recommendations largely related to improving FDA's policies and procedures, and FDA generally agreed with OIG's conclusions.

IV. WITNESSES

The following witnesses have been invited to testify:

Douglas Stearn
Director
Office of Enforcement and Import Operations
Office of Regulatory Affairs
U.S. Food and Drug Administration

Gloria Jarmon
Deputy Inspector General for Audit Services
Office of Inspector General
U.S. Department of Health and Human Services

[13] U.S. Department of Health and Human Services, Office of Inspector General, *The Food and Drug Administration's Food-Recall Process Did Not Always Ensure the Safety of the Nation's Food Supply* (Dec. 2017) (A-01-16-01502).

[14] *Id.*

[15] *Id.*